Endovascular Intervention

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POSTERS

TCT-511

Percutaneous Transluminal Angioplasty of the Subclavian Arteries. Long-Term Follow up.

Isabelle P. henry[1], Amira Benjelloun[2], Michel C. henry[3]
[1]Polyclinique Bois Bernard, Bois Bernard, France, [2]Clinique Coeur et Vaisseaux, Rabat, Morocco, [3]Cabinet de cardiologie, Nancy, France

Background: To review feasibility, safety and long-term results of subclavian artery angioplasty.
Methods: 407 patients (males: 245, mean age: 66.1 ± 12 y) underwent percutaneous treatment for subclavian artery (SA) occlusive disease (stenosis: 295, occlusion: 112). Left: 312, Right: 95, Innominate Artery: 28. Etiology: atheromatous: 397, others: 10 (Takayasu: 6) Mean % stenosis 83.4 +/- 7.8. Mean lesion length: 23.9 +/- 8.7 mm Indications for treatment were upper limb ischemia (ULI) (n=177) Vertebrobasilar insufficiency (VBI) (n=157), associated VBI and ULI (n=123), coronary steal syndrome (n=20) asymptomatic patients with severe coronary disease (n=73) 39 patients had associated Vertebral Artery stenosis, 81 carotid stenoses. 337 prevertebral lesion, 45 post vertebral, both 25. Access: femoral (n=287), brachial (n=81), both (n=39). "Pull through technique": 8 cases. An isolated balloon angioplasty was performed in 59 cases and 348 stents were implanted (balloon expandable: 276, self expandable: 72).
Results: Technical success was obtained in 387 lesions (95 %) 100% for stenoses. Only 92 occlusions were recanalized (82 %). Four periprocedural events occurred (1.2 %), 1 major (fatal stroke), 1 T.I.A., 2 arterial thromboses. During the follow-up (mean follow-up: 75.7 months ± 38.5), we had 40 restenoses (10 %). 13 occurred following angioplasty alone (18.8 %) and 27 following angioplasty and stent implantation (7.8 %) ($P<0.01$). 10 were treated by new angioplasty alone, 30 by repeat stent implantation. Primary (PI) and secondary (PII) patencies on an intention to treat basis at 10-year follow-up were 80.2 % and 86.5 % respectively. In patients without initial stent placement, the rates were 67.5 % and 75.5 % while in those with stents, the rates rose to 91.5 % and 98.2 % ($P < 0.01$). PI for all recanalized lesions were 85.8 %, 79.1 % without stent, 91.8 % with stent ($P < 0.04$) and PII 92.8 %, 88.5 %, 98.1% respectively ($P < 0.02$).
Conclusions: P.T.A. is currently the treatment of choice for subclavian artery lesions. It is a safe and effective procedure associated with low risks and good long-term results. Stents seem to limit the restenosis rate and improve long-term results.

TCT-512

RENAL ANGIOPLASTY AND STENTING. LIMITATIONS. ROLE OF EMBOLIC PROTECTION DEVICES

Isabelle P. Henry[1], Amira Benjelloun[2], Michel C. Henry[3]
[1]Polyclinique Bois Bernard, Bois Bernard, France, [2]Clinique Coeur et Vaisseaux, Rabat, Morocco, [3]Cabinet de cardiologie, nancy, France

Background: Despite good immediate and long-term results, post procedural deterioration of the renal function (RF) may occur after Renal Artery Angioplasty and Stenting (RAAS) in 20-40 % of the patients, which limits the immediate benefits of the technique. Atheroembolism seems to play an important role. We evaluate feasibility and safety of RAAS utilizing a distal protection device (DPD) to reduce the risk of atheroembolism and avoid deteriorations of the RF.
Methods: 171 RAAS performed under DPD in 151 hypertensive patients (M:102). Mean age: 65.2 ± 10.8 yrs with atherosclerotic renal artery stenosis (20 bilateral). 11 pts had solitary kidneys, 62 renal insufficiencies. We used occlusion balloon (n = 46) or filters (n = 125). We recently experimented and treated 12 patients with a new filter the Fibernet (Lumen Biomedical Plymouth MN) which can capture particles of 40µ without compromising the flow. Generated debris removed and analyzed. Blood pressure and serum creatinine levels followed. Techniques of RAAS under protection, limitations will be discussed.
Results: Immediate technical success: 100 %. Visible debris aspirated with Percusurge from all patients. Mean particle number: 98.1 ± 60.00. Mean diameter: 201.2 ± 76µ (38-6206). With current filters debris were removed in 80 % of the cases. With the Fibernet visible debris were removed in all cases. Mean debris surface area: 121mm^2. Mean number of particles 28-60µ : 2136 ± 776, >60µ. We observed one acute RF deterioration. Mean follow-up: 32.2 ± 17 months. Mean creatinine level remains constant during follow-up. At 6 months (131 patients) 95 patients stabilized, 35 with baseline renal insufficiency improved and we had only one RF deterioration (1 %) in a patient with moderate renal insufficiency. At 2 years (105 patients) 73 stabilized, 28 improved and we only had 4 RF deterioration (4 %).
Conclusions: This study demonstrates the feasibility and safety of DPD during renal interventions to protect against atheroembolism and seems to avoid RF deterioration after the procedure and in the long-term. Indications will be discussed. Improvements in DPD for renal stenting are mandatory. Randomized studies are awaited.

TCT-513

RENAL ARTERY ANEURYSMS. FIRST HUMAN TREATMENT WITH THE MULTILAYER FLOW MODULATOR

Michel C. Henry[1], Amira Benjelloun[2], Isabelle P. Henry[3], Antonios Polydorou[4]
[1]Cabinet de cardiologie, nancy, France, [2]Clinique Coeur et Vaisseaux, Rabat, Morocco, [3]Polyclinique Bois Bernard, Bois Bernard, France, [4]Panteleimon General Hospital, Athens, Greece

Background: Renal Artery Aneurysms (RAAs) can be surgically treated but due to high risk, endovascular procedures have been proposed (coils, graft…). All these techniques have some drawbacks, potential complications and contraindications. We propose a new technique: the Multilayer Flow Modulator (MFM*), a self expandable.
Methods: This MFM* is a 3D braided tube made of several interconnected layers without any covering. Our earliest tests, in vitro (theoretical simulation computerized Fluid dynamics, Molecular Modelization) & in vivo. demonstrate that this MFM* reduces the velocity in the aneurismal sac up to 90% by modifying the hemodynamic conditions.. A saccular aneurysm (A.) without collateral branch will thrombose quickly. If a collateral branch is present the flow is directed towards this branch leading to shrinkage of the aneurysm. In fusiform A. the flow is laminated, the vortexes eliminated, eliminating the risk of rupture. Animal experiments show excellent results. Moreover, as demonstrated in animal and human studies this MFM preserves the collateral branches and increases the flow in them, allowing the possibility to cover any artery without compromising the flow.
Results: 8 RAAs (right:5, left: 3) in 8 pts (male: 3) mean age 58 y. treated with MFM* 6 pts had atheromatous disease, 2 a fibromuscular dysplasia. One pt had a solitary kidney. All these pts had hypertension. 10 MFM*(Ø: 5 to 6 mm, length 30 to 60 mm) loaded in a 6 F sheath implanted by femoral approach through 8 F guiding catheter. These stents covered major renal branches without compromising the flow. Technical success: 100%. No complications. Immediately: important reduction of the velocities inside the aneurismal sac. 6 to 36 month follow up will be presented. All aneurysms thrombosed with diameter reduction in some pts. The thrombosis could take several weeks depending on the importance of collateral branches. All the side branches remain patent.
Conclusions: The MFM* is a new technique which seems promising to treat RAAs. Collateral branches can be covered without compromising the flow and risk of renal infarction. It is a safe procedure with a very low complications rate. Larger study is ongoing.

TCT-514

The Multilayer Flow Modulator Stent for the Treatment of Popliteal Aneurysm.

Michel C. Henry[1], Amira Benjelloun[2], Isabelle P. Henry[3]
[1]Cabinet de cardiologie, nancy, France, [2]Clinique Coeur et Vaisseaux, Rabat, Morocco, [3]Polyclinique Bois Bernard, Bois Bernard, France

Background: Popliteal Artery Aneurysms (PA) are traditionally treated surgically. Endovascular procedures with implantation of stent grafts or covered stents have been proposed as an alternative to surgery. Results are encouraging but some problems remain (aneurysm rupture, endoleaks, collateral branch thrombosis…). We used a new concept of stent, the Multilayer Flow Modulator (MFM*) to treat aneurysms and try to avoid some drawbacks encountered with endografts.
Methods: This MFM* is a 3 Dimensional braided tube made of several interconnected layers without any covering. Our earliest tests in vitro (theorical simulation, computerized Fluid dynamics, Molecular Modelization) and in vivo demonstrate that this MFM* reduces the velocity in the aneurismal sac up to 90% by modifying the hemodynamic conditions. A saccular aneurysm without collateral branch will thrombose quickly. If a collateral branch is present the flow is directed towards this branch leading to shrinkage of the aneurysm. Animal experiments show excellent results. Moreover, as demonstrated in animal and human studies this MFM* preserves the collateral branches allowing the possibility to cover any artery without compromising the flow (renal, digestive arteries, supra aortic vessels …).
Results: 5 PA were treated with the MFM* (male: 5, mean age: 65 y.) 9 stents (Ø6 to 8 mm, length 40 to 120 mm) were implanted by percutaneous ipsilateral femoral approach through 8F sheath. Technical success in all patients. All aneurysm thrombosed. Mid-term follow up will be presented. No stent fracture. This MFM* seems well indicated for this popliteal location.
Conclusions: A new concept of stent, the MFM* is developed to treat aneurysm. It opens a new approach to treat peripheral aneurysms avoiding most of the

complications encountered with current endovascular techniques. The results obtained seem promising. A larger study is ongoing.

TCT-515

THE MULTILAYER FLOW MODULATOR STENT FOR THE TREATMENT OF THORACO ABDOMINAL AND ABDOMINAL AORTIC ANEURYSMS. MAROCCAN EXPERIENCE

Michel C. Henry[1], Amira Benjelloun[2], Isabelle P. Henry[3]
[1]Cabinet de cardiologie, nancy, France, [2]Clinique Coeur et Vaisseaux, Rabat, Morocco, [3]Polyclinique Bois Bernard, Bois Bernard, France

Background: Thoraco Abdominal Aortic Aneurysms (TAAA) and Abdominal Aortic Aneurysms (AAA) are traditionally treated surgically, but more and more by interventional procedures (endografts, fenestrated, branched grafts, chimney techniques). We used a new concept of stent, the Multilayer Stent Flow Modulator (M.F.M) to treat these aneurysms (A) and try to avoid some major complications.
Methods: This selfexpandable M.F.M is a 3 D braided tube made of several interconnected layers without any covering. We will explain and demonstrate the key principles of the stent leading to thrombosis, shrinkage of the A, eliminating the risk of rupture. Moreover, this M.F.M preserves the collateral branches allowing the possibility to cover any artery without compromising the flow (renal, digestive arteries, supra aortic vessels…).
Results: 10 TAAA, 8 AAA (7 extended to both iliac arteries) treated with MFM in very high risk patients. 53 MFM implanted (1 to 5 per pt). o Technical success: 100% o At 30 days: no neurological complication, branch patency 100%, no death o During the follow up we had 3 deaths not device related. CT scan control performed at 1, 3, 6, 12, 18 months with calculation of A. Diameters and Volumes. o All collateral branches remain patent and we observed a progressive thrombosis and shrinkage of the aneurysmal sac depending on the size of the collaterals. Some patients developed a thrombus after 1 month, some after 6 months and someeven after 18 months. A significant mean diameter reduction was observed between baseline and 6 months: 17,25 mm reduction for the transversal diameter, 13,83 mm for the antero posterior diameter in the TAAA group. Overtime the ratio thrombus volume / Total Volume is increasing and the ratio Residual Flow Volume / Total Volume is decreasing. The problems of thrombosis, shrinkage and volume reduction of the aneurysmal sac will be discussed. The complications rates with M.F.M appear lower in comparison with current endovascular techniques, and with surgery.
Conclusions: The M.F.M represents an alternative to current devices to treat TAAA and AAA. It is a safe procedure with a low complication rate. The first results are promising. A larger study is ongoing.

TCT-516

Argatroban and t-PA During Catheter-Directed thrombolysis for Extensive lower Extremity Deep Venous Thrombosis

Mohsen Sharifi[1], Wilbur K. Freeman[2], Jean Chatham[3], Tahereh Emami[3], Curt Bay[4], Frederic Schwartz[4]
[1]Arizona Cardiovascular Consultants & A.T. Still University, Mesa, AZ, [2]A.T.Still University, Mesa, AZ, [3]Arizona Cardiovascular Consultants, Mesa, AZ, [4]A.T.Still University, Mesa, AZ

Background: Extensive acute deep venous thrombosis (DVT) responds favorably to catheter directed thrombolysis (CDT). Argatroban is an effective parenteral direct thrombin inhibitor which makes it an attractive drug for DVT treatment. There is a paucity of data on the utilization of argatroban in combination with tPA for extensive DVT.
Methods: 35 patients with extensive DVT involving the femoropopliteal and iliac veins underwent PEVI. DVT was bilateral in 24 patients. A 6-8 F sheath was placed in each popliteal vein under ultrasound guidance. DVT had developed within 10 days of major surgery in 7 patients. For maceration of the clot balloon venoplasty was performed in all. Subsequently an infusion catheter was placed through the popliteal sheath(s) and tPA delivered at 1mg/hr for 20-24 hours for unilateral DVT and at 0.75 mg/hr through each infusion catheter for bilateral involvement. For unilateral DVT, argatroban was given at 0.5 -1 mcg/kg/min through the side port of the sheath and for bilateral DVT it was given at 0.3- 0.75 mcg/kg/min. PTT was kept between 50-90 seconds. Every 3 hours the PTT was checked if there was a change in the Argatroban dose. It was checked every 12 hours if the PTT had remained within the therapeutic range. Follow-up venography was performed between 20- 30 hours after PEVI.
Results: With the above regimen there were no bleeding complications even in the 7 patients with recent surgery. Complete or significant resolution of thrombus was noted in 32patients (91%). In 3 patients who previously had occlusive thrombus within their IVC filter, the iliac and femoropopliteal DVT had resolved, however some degree of thrombus in the IVC filter persisted. These were treated with further thrombectomy and the procedure terminated at that time with removal of the sheaths.
Conclusions: CDT using a combination of low dose argatroban and tPA is highly effective and safe in the treatment of massive diffuse DVT. The unacceptably high rates of bleeding previously reported are not applicable to the contemporary era. A synergistic effect exists between argatroban and tPA which make them an ideal anticoagulant- thrombolytic combination for CDT.

TCT-517

Reduction of Hospitalization and Duration of Anticoagulation for Deep Venous Thrombosis in Patients Undergoing Percutaneous Endovenous Intervention and Receiving Novel Anticoagulants

Mohsen Sharifi[1], Wilbur K. Freeman[2], Nikki Rezania[3], Tahereh Emami[4], Jean Chatham[4], Frederic Schwartz[5]
[1]Arizona Cardiovascular Consultants & A.T. Still University, Mesa, AZ, [2]A.T.Still University, Mesa, AZ, [3]Arizona Cardiovascular Consultants & Vein Clinic, Mesa, AZ, [4]Arizona Cardiovascular Consultants, Mesa, AZ, [5]A.T.still University, Mesa, AZ

Background: The current recommendation for the treatment of deep venous thrombosis (DVT) is at least 5 days of parenteral anticoagulation with a minimum of 24 hours of overlap with a vitamin K antagonist at a therapeutic INR. It has been well established that percutaneous endovenous intervention(PEVI) reduces the sequelae of DVT by early removal of thrombus. The efficacy and safety of novel anticoagulants rivaroxaban and dabigatran following PEVI has not been investigated.
Methods: 93 patients with femoropopliteal , iliac , upper extremity and internal jugular DVT who had undergone PEVI underwent initiation of dabigatran (34 patients) or rivaroxaban (59 patients) within 2 hours after their procedure. No parenteral anticoagulation was given when oral anticoagulants were started. The mean follow up was 18±3 months. Aspirin at 81mg daily was given to 18 patients who had received an endovenous stent and was continued for 1 month. The patients were evaluated for recurrent venous thromboembolic (VTE) disease and bleeding during the follow- up period.
Results: There was no bleeding or recurrent VTE in any patient. Two patients could not tolerate dabigatran due to gastrointestinal side effects. The mean duration of parenteral treatment was 31±5 hours. Enoxaparin was the parenteral anticoagulant in 32 patients and unfractionated heparin in the remainder. The mean duration of hospitalization was 29±5 hours. At follow-up 3 patients died due to cancer.
Conclusions: In patients undergoing PEVI, the duration of safe and effective parenteral anticoagulation is less than the traditionally accepted minimum of 5 days. Initiation of rivaroxaban or dabigatran soon after PEVI promotes early discharge and obviates the inconveniences associated with regulation of INR.

TCT-518

One-Year Results of the Multi-layer Flow Modulator Stent in the Management of Thoracoabdominal Aortic Aneurysms.

Sherif Sultan[1], Niamh Hynes[1]
[1]Western Vascular Institute, Galway, Ireland

Background: We present the first 55 cases of MFM implanted under indication for use to treat aortic disease. All were done on compassionate basis, in 11 countries. Primary Endpoints are Freedom from Rupture and Aneurysm-related Death.
Methods: They were 31 Crawford Thoraco-abdominal (8 Type I, 3 Type II, 9 Type III, and 11 Type IV), 7 arch, 3 abdominal, 8 suprarenal aortic aneurysms and 6 type B dissections. Mean age of 64.5 years +/- 18years; mean aneurysm diameter was 6.04cm+/-1.66cm (Median 5.76cm). Mean number of side branches covered was 3.7 per case (median 4, range 0-6). Total 108 stents used, mean of 1.96 MFM per case.(Median 2, range 1-5)
Results: One-year Aneurysm-related survival was 93.7% (SE+/-4.44%). No rupture occurred. Technical success was 98.2%. One-year all-cause survival was 84.8% (SE+/-6.25%). There was no paraplegia. No peri-operative visceral insult. At 12 months all 202 side branches were patent. No stent fractures. One-year intervention-free survival was 92.4% (SE+/-5.09%) At six months mean rate of sac volume increase was 0.36% per month. At twelve months the rate of increase had slowed to 0.28% per month. The ratio of thrombus to total volume stayed almost constant over the 12 months at 0.48, while the ratio of flow to total volume fell from 0.21 to 0.12 at 12 months.
Conclusions: Increasing sac size did not herald rupture. MFM implantation instigates a process of aortic remodeling involving initial thrombus deposition, which slowed between six and twelve months .The MFM was not associated with loss of native side branches.

TCT-519

Comparison of Wound Healing in Critical Limb Ischemia according to Wound Types with and without Successful Revascularization

Norihiro Kobayashi[1], Toshiya Muramatsu[1], Reiko Tsukahara[1], Yoshiaki Ito[1], Hiroshi Ishimori[1], Keisuke Hirano[1], Masatsugu Nakano[1]
[1]Saiseikai Yokohama-city Eastern Hospital, Yokohama, Japan

Background: To achieve successful revascularization is important for wound healing in critical limb ischemia (CLI) with tissue loss following endovascular therapy (EVT). However, we sometimes experience failure to achieve wound healing even after successful EVT. We investigated the relationship between wound healing and successful revascularization according to wound types.
Methods: Between April 2007 and April 2012, 171 CLI patients (204 limbs) classified to Rutherford 5 or 6 were treated by EVT in our institute. In these limbs, 199 individual wounds exited on foot and were evaluated wound healing rates and time to healing according to their wound types with and without successful revascularization. Wound types were divided into three groups, group T (Toe wound, n=128), group H

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